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DuPont Consumer Health 0882 '99 AUG 20 P1:31

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Mr. Joseph A. Levitt, Director
Center For Food Safety and Applied Nutrition
Dockets Management Branch (HFA-305)
Food and Drug Administration,
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Dear Mr. Levitt:

DuPont is a science-based company, delivering solutions that make a difference in people's lives in food and nutrition; health care; apparel; home and construction; electronics; and transportation. Founded in 1802, the company operates in 65 countries and has 92,000 employees. In addition to DuPont's research and development of prescription pharmaceuticals, DuPont develops and sells a wide variety of food ingredients based on soy and is doing research in food ingredients derived from other crops. DuPont has a collaboration with WebMD, an internet portal that is increasingly a source of health information for consumers.

DuPont welcomes the opportunity to respond to FDA's request for comment regarding its regulation of dietary supplements. Our basic beliefs are that such products should promote better health, be safe, be manufactured to appropriate standards and specifications, and that such products must not be labeled or promoted to encourage inappropriate consumer reliance on such products when the consumer requires the attention of a trained health professional. Having stated these beliefs, we will turn to the questions where you have requested comment.

Question 1. In addition to ensuring consumer access to safe dietary supplements that are truthfully and not misleadingly labeled, are there other objectives that an overall dietary supplement strategy should include?

DuPont believes that an overall dietary supplement regulatory strategy should recognize the following realities and include the following elements:

1. A certain percentage of consumers expect choice and an opportunity to evaluate alternatives to Western remedies and diet.

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2. Regulatory efforts that are perceived to restrict choice and availability without good reason will meet with resistance. On the other hand, we believe that there are issues involving dietary supplements where regulation can be justified to the consumer and in those areas, the FDA should be active.

3. We believe that industry should embrace certain principles regarding what consumers should expect from dietary supplements and these expectations should be reflected in the FDA's regulatory approach to dietary supplements.

These principles are as follows:

(i) Health and disease should be viewed as biological continuums rather than categories, and health can be managed by the consumer when they are provided with the appropriate information and products to do so.

(ii) Dietary supplements should be safe when consumed as directed. This being said, individual variation in human biology and response need to be recognized and the consumer alerted accordingly. The possibility of adverse reactions, cautionary statements about potential interactions with drugs, and hazards to women of child-bearing potential should be included in product labels. If a product (such as a botanical or a concentrate or an isolate) is recommended for consumption in quantities greater than those encountered in a traditional diet or through historical use, appropriate safety assessment studies should be conducted at multiples of the recommended consumption level to ensure appropriate margins of safety.

(iii) Structure and function claims should be judged by the FDA on the basis of scientific data. In addition, the FDA should take into account the totality of information that is available about the product to the "reasonable consumer". The FDA should consider requiring different levels of substantiating data for different levels of health benefit claims up to and including appropriately designed and statistically powered clinical trials. Such a proposal is being considered by other countries such as Canada and within the European Union. Careful wording of structure and function claims should not permit a supplier to avoid regulation as a drug when the intended use suggests otherwise.

(iv) Dietary supplements should be used by the consumer to maintain or enhance their health rather than to treat disease. Products should not be promoted directly or indirectly for the treatment of disease. The FDA should evaluate whether current disclaimers are sufficient to deter inappropriate reliance on dietary supplements to treat, cure or prevent disease. If the FDA determines that a dietary supplement is being widely and inappropriately used for the treatment of disease based on the totality of the information that is available to the consumer about the product, the FDA should have the power to regulate such product as a drug. Current labeling practices should include statements which encourage consumers who believe they have a disease to seek advice and treatment from a trained health care professional.

(v) Dietary supplements should be manufactured and labeled so that customers receive the product they expect. Products should have a uniform level of quality and bioactivity from lot to lot, and not be adulterated or otherwise dangerous. The manufacturing processes and quality standards for dietary supplements should include a measurement of the bioactivity underlying the claimed health benefit of the product. The FDA and the industry should recognize that not all varieties of a given herb or botanical are the same and that some varieties may have benefits and risks that are not shared by other varieties. Likewise, the time of harvest and the method of processing may affect the properties of a dietary supplement. If a clinical benefit is established for a food or dietary supplement, then all such products that are marketed in association with such a claim should be shown to have the same properties as the product that was tested. Technologies should be developed and employed to test for such consistency.

Question 2. Are the criteria for prioritizing the tasks within the supplement strategy appropriate? Which specific tasks should FDA undertake first?

DuPont believes that FDA should prioritize their tasks on the basis of 1) product safety, 2) manufacturing, and 3) labeling.

Question 3. What factors should FDA consider in determining how best to implement a task (i.e., use of regulations, guidance, etc.)?

The factors the FDA should consider are 1) the risk to public safety due to the use of dietary supplements, 2) the level of consumer knowledge regarding the safe and appropriate use of dietary supplements, 3) the ability of the dietary supplement industry to self-regulate. Additional regulation should be considered at such time as the FDA can cite specific problems with the current regulatory scheme and at such time as the public is more likely to be aware of the need for additional regulation of the dietary supplement industry. The FDA should consider consumer education programs developed in cooperation with those members of industry who share its objectives as an important means toward implementation of strategy. Well publicized enforcement in egregious cases should be a secondary strategy.

Question 4. What tasks should be included under the various dietary supplement program elements in the CFSAN 1999 Program Priorities document?

1. Establish a confidential premarketing notification process which includes submission of substantiating data regarding product safety, bioactivity, and quality control measures.
2. Establish a stronger process for collection, validation and dissemination of data concerning consumer adverse experiences that are associated with dietary supplements.

Question 5. Are there current safety, labeling, or other marketplace issues that FDA should address quickly through enforcement actions to ensure, for example, that consumers have confidence that the products on the market are safe and truthfully and not misleadingly labeled?

Any case of mislabeling of contents, or example of product contamination should be the subject of immediate and well publicized enforcement. The public is more likely to be sympathetic to such enforcement than efforts to regulate structure and function claims that are in the gray area. Egregious promotional claims for the treatment of disease should be prosecuted with the same degree of vigor as the FDA would seek prosecution of a pharmaceutical company for a promotional claim that was false or misleading.

Question 6. Toward what type or area of research on dietary supplements should FDA allocate its research resources?

DuPont believes FDA should devote its research resources to the following areas:

- 1) The evaluation of potential interactions between dietary supplements and prescription drugs
- 2) The development of dose-response profiles for the most commonly used dietary supplements
- 3) The identification and use of surrogate or biomarkers of health, e.g., the capacity of the body's antioxidant system; the identification of such markers could provide regulatory guidance for the certification and standardization of products and also enable the consumer to make informed decisions about the selection and continued use of products.
- 4) The development of sophisticated analytical and functional assessment methodologies for the evaluation of mixtures found in dietary supplements
- 5) The assessment of the extent to which consumers are appropriately relying on dietary supplements to manage their health or inappropriately relying on them to manage disease; such studies would provide valuable information and insight as to the utility of current disclaimers and the need for consumer education to ensure that dietary supplements are seen as complimentary to, not replacements for, our current standards of medical care

Question 7. Given FDA's limited resources, what mechanisms are available, or should be developed, to leverage FDA's resources to meet effectively the objective of the strategy?

The FDA should work with industry leaders to promote the safe and appropriate use of dietary supplements.

The FDA should sponsor conferences on high priority issues and invite press coverage so that consumers can be educated concerning the proper use, and improper reliance on, dietary supplements.

Thank you for your consideration of the foregoing. We would be glad to answer any questions that you might have and participate in future discussion of these important issues.

Very truly yours,

A handwritten signature in cursive script, reading "Peter J. Gillies".

Peter J. Gillies, Ph.D.
Global Director, Scientific Affairs
DuPont Consumer Health

A handwritten signature in cursive script, reading "Carl G. Bartholomaeus".

Carl G. Bartholomaeus
Corporate Counsel

